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10/574,046	01/31/2007	Lynn Dickey	040989/309915	9129
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,046

Applicant(s)

DICKEY ET AL.

Examiner

Bruce D. Hissong, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34 and 90-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34, 90-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

1. Applicants' response to the office action mailed on 6/23/2009, including arguments/remarks and amended claims, was received on 10/23/2009 and has been entered into the record.

2. In the response received on 10/23/2009, the Applicants cancelled claims 1-29 and 35-89, and added new claims 90-99. Claims 30-34 and 90-99 are therefore pending, and are the subject of this office action.

Claim Objections

Objection to claims 30-34 for depending from non-elected claims, as set forth on page 2 of the office action mailed on 6/23/2009, is withdrawn in view of Applicants' amendments to the claims to present them in independent form for claims 30-32, and to depend from claim 30 for claims 33-34.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of claims 44-48 and 71-75 under 35 U.S.C. 101, as being directed to non-statutory subject matter, as set forth on page 3 of the office action mailed on 6/23/2009, is moot in view of Applicants' cancellation of these claims.

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Rejection of claims 44-46, 49-57, 71-73, and 76-84 under 35 USC § 112, first paragraph, regarding lack of enablement for interferon (IFN)- α -2b polypeptides comprising unlimited carboxy truncations, as set forth on pages 3-4 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of these claims. Furthermore, rejection of claims 51-52, 57, and 78-79 for lacking enablement for all possible host cells comprising a vector encoding a truncated IFN- α -2b polypeptide, as set forth on page 4 of the office action mailed on 6/23/2009, is moot in view of the cancellation of these claims.

2. Rejection of claim 34 under 35 USC § 112, first paragraph, regarding lack of enablement for all possible host cells comprising a vector encoding a truncated IFN- α -2b polypeptide, as set forth on page 4 of the office action mailed on 6/23/2009, is withdrawn in response to Applicants' amendment to the claim to recite "An isolated host cell".

Claim Rejections - 35 USC § 112, first paragraph - written description

Rejection of claims 44-46, 49-57, 71-73, and 76-84 under 35 USC § 112, first paragraph, regarding lack of written description for IFN- α -2b polypeptides comprising unlimited carboxy truncations, as set forth on page 5 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of these claims.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 53 and 80 under 35 USC § 112, second paragraph, as being incomplete for omitting essential method steps, as set forth on page 6 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of these claims.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Rejection of claims 44-46, 49-52, and 57 under 35 USC § 102(e) as being anticipated by Welcher *et al* (US 20050221344), as set forth on pages 6-7 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of the claims.

2. Rejection of claims 44, 49-52, 57, 71, 76-79, and 84 under 35 USC § 102(b) as being anticipated by Franke *et al* (DNA, 1982, Vol. 1, p. 223-230), as set forth on page 7 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Rejection of claims 53-56 under 35 USC § 103(a) as being obvious in view of either Welcher *et al* or Franke *et al*, each in view of Brandle *et al* (US 20030135887), as set forth on pages 8-9 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of the claims.

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2. Rejection of claims 72-73 under 35 USC § 103(a) as being obvious in view of Franke *et al* in view of Welcher *et al*, forth on page 9 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of the claims.

3. Rejection of claims 80-83 under 35 USC § 103(a) as being obvious in view of either Franke *et al* or Welcher *et al*, each in view of Brandle *et al*, as set forth on pages 9-10 of the office action mailed on 6/23/2009, is moot in response to Applicants' cancellation of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejection of claims 53-57 and 80-84 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8, 12, and 14-17 of US Patent 6,815,184, as set forth on pages 10-11 of the office action mailed on 6/23/2009, is moot in view of Applicants' cancellation of these claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-34 and 90-93, and 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franke *et al* ("Franke" - *DNA*, 1982, Vol. 1, p. 223-230) in view of Welcher *et al* ("Welcher" - US 20050221344). Franke and Welcher were both cited in the previous office action.

The claims of the present invention are drawn to isolated polynucleotides encoding the polypeptides consisting of SEQ ID NO: 5 or SEQ ID NO: 10, or alternatively SEQ ID NO: 10 operably linked to a signal peptide. The claims also recite an expression cassette comprising the isolated polynucleotides, and a host cell comprising said expression cassette, wherein said host cells are selected from mammalian cells, plant cells, insect cells, yeast cells, and prokaryotic cells.

In the previous office action, claims 30-34, drawn to isolated nucleotides encoding SEQ ID NO: 10 or SEQ ID NO: 5 (disclosed in the specification as mature or immature IFN- α -2b, respectively, with a 7 amino acid carboxy truncation), were indicated as allowable. However, upon further consideration the subject matter of these claims, as well as dependent claims 90-93 and 95-98, are obvious in view of Franke and Welcher.

Franke teaches a nucleic acid encoding a carboxy-truncated IFN- α polypeptide that is lacking the 11 carboxyterminal amino acids (see p. 227, 1st column, 1st full paragraph). Fig. 4 of Franke teaches that the resulting polypeptide, "A-11" is 154 amino acids, which combined with the missing 11 amino acids, would indicate that the parent polypeptide was 165 amino acids. While Franke does not explicitly state that the carboxy-truncated "A-11" polypeptide is a truncated IFN- α -2b polypeptide, because the parent polypeptide appears to be 165 amino acids it would be apparent, in absence of evidence to the contrary, that the encoded polypeptide of Franke is equivalent to IFN- α -2b. Franke teaches construction of plasmids for expressing nucleotides encoding IFN polypeptides (p. 224, 1st column and p. 226, 1st column), and expression of these IFN-encoding plasmids in *E. coli* (p. 224, 2nd column, 1st full

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paragraph), resulting in production of a carboxy-truncated IFN- α -2b with biological activity (see Table 1).

Welcher teaches IFN polypeptides which may be truncated at the carboxy terminus, and nucleic acids encoding such carboxy-terminated IFN polypeptides (paragraph 0073 and claim 3). Welcher also teaches truncated IFN polypeptides with leader or signal peptides (paragraphs 0175, 0177) and nucleic acids encoding IFN polypeptides with a signal peptide (paragraph 0359), wherein the nucleic acid sequence encoding said signal peptide is positioned at the 5' end of the IFN encoding region. Welcher further discloses nucleic acids encoding truncated IFN with a vector (claim 4) and both prokaryotic and eukaryotic host cells comprising said vector (claims 5-7). Regarding host cells, Welcher teaches that appropriate host cells include bacterial (*E. coli* - paragraph 0188) and numerous mammalian cells (paragraph 0189), as well as plants (paragraphs 0193, 0213). Welcher also claims a process for preparing IFN polypeptides comprising culturing a host cell comprising a vector encoding an IFN polypeptide and isolating said polypeptide from the culture (claim 9).

Therefore, one of ordinary skill in the art, at the time the present invention was conceived, would have been motivated to create nucleic acid molecules encoding truncated IFN- α -2b polypeptides equivalent to the polypeptides of SEQ ID NO: 10 or SEQ ID NO: 5. The motivation to do so comes from the combined teachings of Franke and Welcher, which both teach carboxy-truncated IFN- α polypeptides, including carboxy-truncated IFN- α -2b which exhibits biological activity. Although neither Franke nor Welcher specifically teach the IFN- α polypeptides of SEQ ID NO: 5 or SEQ ID NO: 10, the carboxy-terminus, including the region (11 amino acids) deleted from the carboxy-terminus of Franke's "A-11" polypeptide, that a person of ordinary skill in the art would be motivated to create additional carboxy-truncations at the C-terminus of IFN- α for the purpose of determining the effects of this region of various biological activities. When there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try may show that it was obvious under § 103 (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1397 (2007)).

In the instant case, there is a finite number of amino acids within the carboxy-terminus region of IFN- α , such as the carboxy-terminal 11 amino acids removed from the IFN- α of Franke. Furthermore, as set forth above, there is sufficient motivation provided by Franke and Welcher to create additional IFN- α carboxy-terminated mutants for the purpose of studying the biological role of the carboxy-terminus.

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Therefore, it would be obvious to create nucleic acid encoding a carboxy-truncated mutant of IFN- α , which is truncated by 7 amino acids and which is equivalent to SEQ ID NO: 10. Furthermore, Welcher teaches carboxy-truncated mutants of both mature IFN (lacking a leader sequence) and IFN with a leader sequence (paragraph 0077) with carboxy-truncations, and therefore a person of ordinary skill would also be motivated to create a nucleic acid encoding IFN- α with a leader sequence, wherein this polypeptide is truncated by 7 amino acids at the carboxy-terminus, and wherein this polypeptide would be equivalent to SEQ ID NO: 5.

Finally, because both Franke and Welcher teach nucleic acids encoding truncated IFN- α polypeptides, and vectors and host cells comprising these nucleic acids, including mammalian and plant host cells (Welcher), and various signal peptides (Welcher), one of ordinary skill in the art would be motivated to create nucleic acid molecules encoding the polypeptides of SEQ ID NOs 5 and 10, as discussed above, and would further be motivated to create expression vectors comprising these nucleic acids and host cells, including mammalian and plant host cells, for the purpose of expressing the IFN polypeptides.

2. Claims 94 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franke *et al* ("Franke" - *DNA*, 1982, Vol. 1, p. 223-230) in view of Welcher *et al* ("Welcher" - US 20050221344), and further in view of Raskin (US 6,096,546).

The subject matter of the present invention and the teachings of Franke and Welcher are discussed above. Claims 94 and 99 are drawn to host cells comprising nucleic acids encoding the polypeptides of SEQ ID NOs 5 or 10, wherein said host cells are duckweed cells.

Franke and Welcher teach expression of carboxy-truncated IFN- α polypeptides in various host cells, including plant cells (Welcher), but are silent regarding expression in duckweed. However, Raskin teaches expression of proteins in plants, and specifically teaches expression in duckweed (see claim 5, for example).

Therefore, one of ordinary skill in the art, at the time the present invention was conceived, would have been motivated to create nucleic acids encoding the carboxy-truncated IFN- α polypeptides of SEQ ID NO: 5 or 10, and express these nucleotides in duckweed cells. The motivation to do so comes from the combined teachings of Franke and Welcher, which as discussed above, provide the motivation to create nucleic acids encoding the polypeptides of SEQ ID NOs 5 or 10 and express them in various host cells, including plant cells. Further motivation comes from Raskin, which teaches that duckweed cells are appropriate host cells for protein expression. Therefore, one of ordinary skill in the art would be

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motivated to express the nucleic acids suggested by Franke and Welcher in the duckweed cells taught by Raskin.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong

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/Robert Landsman/
Primary Examiner, Art Unit 1647